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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,727	09/26/2005	Jochen Wonschik	3968.150	8867

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EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/527,727	WONSCHIK ET AL.	
	Examiner	Art Unit	
	Melissa S. Mercier	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Applicants claim of priority to PCT/EP04/01490 filed on February 17, 2004 is acknowledged.

Claims 1-20 are pending in this application. Claims 1-20 are rejected.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claims 1-20, it is unclear to the examiner what the ratio of shell thickness to diameter of coating free capsule is. The range of 0.004-0.04 is claimed.

The examiner is interpreting this to be 0.004:1 to 0.04:1. Clarification is requested. Claims 2-20 are including in this rejection since they carry all the limitations of claim 1. While Claim 5 further limits the ratio claimed, it is unclear for the reasons set forth above.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation a diameter of 4.5-6.5mm, and the claim also recites preferably 4.5-5.5mm which is the narrower statement of the range/limitation.

Additionally, claim 5 recites the broad recitation of a thickness of the shell in the range of 50-150um, and the claim also recites, preferably 50-90um.

Claim 5 further recites the broad recitation of the shell thickness to capsule diameter ratio is 0.01 to 0.03, and the claim also recites, preferably 0.01 to 0.02.

Regarding claim 8, it is unclear what the identifier (b) is intended to indicate. The examiner is interpreting the limitation of this claim to be "a spherical capsule of claim 7, further comprising a gelatin having a Bloom value of 0 or a fish gelatin having a Bloom value of <200". Clarification is requested.

Claim 9 recites the limitation "the fish gelatin" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite the limitation of a fish gelatin.

Further regarding Claim 9, it is unclear whether the capsule further comprises a cold water fish gelatin with a gel point of <20C **OR** a fish gelatin with a gel point of <20C, **OR a** mixture of the 2.

Regarding Claim 11 recites the broad recitation of the concentration of the plasticizer is 10-30% (m/m), and the claim also recites, preferably 15-20% (m/m).

Regarding claims 12 and 14, the phrase "preferably selected from" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-6, 11-12, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapler et al. (US Patent 5,286,496) in view of Rowe et al. (US Patent 6,200,603).

Stapler discloses, "microcapsules which contain breath control actives/antimicrobials in the core of the microcapsule along with an organic diluent as well as in the shell of the microcapsule" (column 1 line 65 to column 2, line 2).

Additionally, "the shell material of the microcapsules can be any materials which are suitable for ingestion as well as retention in the oral cavity, including gelatin, polyvinyl alcohols, waxes, gums, sucrose esters and sugar candy type materials used in cough drops and mints" (column 2, lines 11-16). The thickness of the shell is discloses in the range of 30um to 2mm (column 2, lines 19-20). The particle diameter is in the range of about 2mm to about 9mm (column 2, lines 23-25). Therefore the ratio of thickness of the shell to particle diameter would fall within the claimed values of 0.004 to 0.04:1.

Stapler further discloses, "flavoring agents such as thymol, eucalyptol, menthol, methyl salicylate or witch hazel. These agents are used in an amount of from about 0.1% to about 25%" (column 3, lines 60-65).

Stapler does not disclose the microcapsules being coated or gel points of the gelatin and plasticizer.

Rowe discloses, "a coated capsules comprising a gelatin shell with a flavored coating. A sugar or sugar substitute is included in the material of the shell and that of the coating to stabilize both compositions and the junction there between" (abstract).

Additionally, "the sugar or sugar substitute can include a variety of sugar alcohols or non-reducing saccharides, including sorbitol; polyglycerol; mannitol; xylitol; maltitol; isomalt; and corn syrup (column 3, lines 3-10). Rowe discloses, "the finished capsule shell formulation comprises 65-70% gelatin, 22-25% glycerin, and 8-10% water" (abstract). According to Rowe, the amount of gelatin, water, and plasticizers, such as glycerine preserve a degree of softness and flexibility of the shell (column 1, lines 33-

36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the percentage of each in order to make a capsule with the properties desired. Additionally, it would be obvious to one of ordinary skill in the art to modify the percentage of plasticizer and the type of plasticizer in order to obtain a specific gel point. It would be within the knowledge of the person of ordinary skill in the art at the time the invention was made to do so in order to obtain a shell with the desired properties of hardness and strength. It is the examiners position that a gel point is a property, which can be modified in order to obtain a capsule with the desired properties and qualities.

Additionally, Rowe discloses, "it is desirable to minimize the quantity of shell material in the coated product, and in this respect it is recognized that with a sufficiently stable interface and bond between the coating and shell, the coating will serve to reinforce the shell, and the shell to effectively seal the coating. Thus, if the shell thickness can be reduced such that its entire thickness is effectively bonded to the coating, then the resultant product will include a bare minimum of shell material" (column 3, lines 38-35). Therefore, it is the examiners position that if it were desirable to keep the shell to a minimum as disclosed by Rowe, the diameter of coated capsules would be similar to those disclosed by Stapler. Additionally, it is also the examiners position that since the purpose to the coating is to reinforce the shell, it would be within the knowledge of one of ordinary skill in this art at the time the invention was made to modify the coating layers and thickness in order to make a stable product.

Claims 2-4, 7-8, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapler et al. (US Patent 5,286,496) in view of Rowe et al. (US Patent 6,200,603) and Matthews et al. (US Patent 4,816,259).

The teachings of Stapler and Rowe are discussed above and applied in the same manner.

Stapler and Rowe do not disclose an intermediate layer of coating or the Bloom value of the gelatin used.

Matthews discloses, soft gels comprising "a gelatin mass that produces a smooth completely dispersed gelatin suspension. The gelatin required for this dispersion should be between 130 bloom and 200 bloom alkali based skin or bone type" (column 2, lines 36-30). Matthew's examples further disclose an enteric-coated soft gelatin capsule made from a gelatin with a bloom value of 150, and a hard gelatin capsule made from a gelatin with a high bloom value. Therefore, it is the position of the examiner that like the gel point, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected of a gelatin with a specific bloom value in order to obtain the desired rigidity of the capsule shell.

Additionally, Matthew's discloses, "after the capsules are air dried, any one of several known coating solutions may optionally be applied to the capsule shell to improve its surface appearance or to render the capsule moisture proof. For example, a coating of confectioners glaze (food grade shellac) dissolved in alcohol may be applied in an amount sufficient to completely cover all surfaces of the capsules. About one to three applications of glaze are usually sufficient to insure adequate dryness, but more or

less may be applied. The capsules are again air dried to remove the alcohol solvent (column 2, lines 45-55).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Matthew's with the capsules taught by Stapler and Rowe in order to make capsules which can be used as enteric coated capsules. Additionally Matthew's discloses that such capsules "exhibit an improved mechanical strength and will not crack or undergo substantial deformation during standard large scale capsule manufacturing procedures" (column 1, lines 63-67).

A person of ordinary skill in the art would have a reasonable expectation of success in making the capsules since Stapler, Rowe and Matthews all teach similar capsules as those of the instant claims, with the same intended function.

Claims 9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapler et al. (US Patent 5,286,496) in view of Rowe et al. (US Patent 6,200,603) and Alamian et al. (US Patent 6,770,311).

The teachings of Stapler and Rowe are discussed above and applied in the same manner.

Stapler and Rowe do not disclose a source of the gelatin used.

Alamian discloses, "granules having a shell with a gelled center, derived from an aqueous mixture containing food grade encapsulation materials, such as water-soluble carregeenans or gelatin. The mixture is introduced in the form of droplets into food grade oil, the temperature of which, at least in its lower layers, is below the temperature

at which the droplets congeal to form granules. The thus-formed granules have an outside shell" (column 1, line 57 through column 2, line 5).

Additionally, Alamian discloses, "the food grade encapsulation materials must be able to form a shell, such as gelatin, beef gelatin, fish gelatin, pork gelatin, alginates, and gellan gum" (column 2, lines 34-52).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Stapler and Rowe with the teachings of Alamian since the encapsulation material must have the ability to form a shell or membrane, be stable at temperatures between –10C to 80C and must be light. It would be within the knowledge of one of ordinary skill in the art to select a gelatin, which would create a shell with the qualities desired. Additionally, it is the examiners position that each type of gelatin would have different bloom values and different gel points, therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have selected the gelatin to best fit the qualities to be obtained.

A person of ordinary skill in the art would have a reasonable expectation of success in making the claimed capsules since all cited references teach capsules with a gelatin shell.

Claims 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapler et al. (US Patent 5,286,496) in view of Rowe et al. (US Patent 6,200,603) and Greenberg (US Patent 5,378,131).

The teachings of Stapler and Rowe are discussed above and applied in the same manner.

Stapler and Rowe do not disclose the use of thaumatin, neohesperidine, or miraculin as sweeteners.

Greenberg discloses a chewing gum comprising sweeteners, including sucralose, aspartame, salts of acesulfame, thaumatin, and saccharine and its salts (column 6, lines 1-5).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Stapler and Rowe with the sweeteners taught by Greenberg, since Greenberg discloses, "in order to provide longer lasting sweetness and flavor perception, it may be desirable to encapsulate the artificial sweetener" (column 6, lines 6-9).

One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success since Stapler and Rowe both disclose the use of a sweetener and Greenberg discloses the use high intensity artificial sweeteners to be encapsulated.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stapler et al. (US Patent 5,286,496) in view of Rowe et al. (US Patent 6,200,603) and Winston Jr. et al. (US Patent 5,342,626).

The teachings of Stapler and Rowe are discussed above and applied in the same manner.

Stapler and Rowe do not disclose the use of 0.4-3% gellan gums in the shell.

Winston discloses a polymer composition comprising 0.1 to 50% gellan gum to be used as flexible films for encapsulation (abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used gellan gum in the shell of the capsules taught by Stapler and Rowe. Winston discloses compositions comprising the gellan gum "have numerous advantages including biodegradability, strength, thermal reversibility, water solubility, and reducing processing time" (column 3, lines 2-6).

A person of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success since the use of gellan gum is well known in the art to be useful as a thickener or gelling agent.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stapler et al. (US Patent 5,286,496) in view of Rowe et al. (US Patent 6,200,603) and Schlameus et al. (US Patent 4,888,140).

The teachings of Stapler and Rowe are discussed above and applied in the same manner.

Stapler and Rowe do not disclose a method of making the capsules comprising the steps of:

a. pumping the core material and a curable shell simultaneously through a concentric multi-component nozzle so that they drip into a cooling liquid with the formation of a capsule;

b. drying the capsules;

c. coating the dried capsules

Schlameus discloses, "a process for preparing round, fluid filled microcapsules by the simultaneous extrusion, of core and shell material from coaxially aligned and concentric extrusion nozzles into a surrounding carrier fluid moving in the direction of the extrusion wherein a surfactant having affinity with the carrier fluid is added to the carrier fluid" (abstract). The microcapsules are placed into a reservoir holding a cold carrier fluid (column 2, lines 2-4).

Schlameus discloses dry weight yields of the process were discussed (column 2, lines 14-21), which would require the microcapsules were dried.

Schlameus does not disclose the coating of the dried capsules. However, Rowe discloses, "a coating can be applied wet, as in a pan coating process" (column 3,lines 23-24).

It would be obvious to a person of ordinary skill in the art at the time the invention was made to have combined the method of Schlameus with the coating method of Rowe. Schlameus discloses, the capsules produced by his method have increased burst strength and Rowe discloses the pan coating process assists in stabilizing the interface between the coating and shell.

A person of ordinary skill in the art would have a reasonable expectation of success in making the capsule of Stapler and Rowe with the method of Schlameus since the combined teachings disclose a core with a shell and a coating used to stabilize the shell.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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